UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,711	07/17/2003	Te-Yen Chien	AGIL-0043	1537

23377 7590 08/04/2006

WOODCOCK WASHBURN LLP
ONE LIBERTY PLACE, 46TH FLOOR
1650 MARKET STREET
PHILADELPHIA, PA 19103

EXAMINER
GHALI, ISIS A D

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/621,711	CHIEN, TE-YEN	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *163-174* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *163-174* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03/03/04; 12/08/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's preliminary amendment filed 05/15/2005; IDS filed 12/08/2004; and IDS filed 03/03/2004.

Claims 163-174 are pending and included in the prosecution.

Specification

1. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

2. The use of the trademarks "DuroTak" and "PVP/VA-S630" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 163-174 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 7,045,145. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed subject mater is fully claimed and covered by the claims of the issued patent 7,045,145. The present claims and the claims in the issued patent are directed to common subject matter as follows: a transdermal delivery system comprising backing layer and adhesive polymer matrix layer affixed to the backing layer, wherein the adhesive polymer matrix comprising an adhesive polymer, a humectant, an estrogen, a progestin, and a combination of permeation enhancers comprising dimethyl sulfoxide, a fatty acid (C_8-C_{20}) alcohol ester of lactic acid, a lower (C_1-C_4) alkyl ester of lactic acid, and capric acid. The adhesive matrix is polyacrylate copolymer of 2-ethylhexyl acrylate and vinyl acetate and the humectant is polyvinyl

pyrrolidone copolymer with vinyl acetate. The estrogen is 17-β-estradiol and progestin is levonorgestrel.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 163-166 and 171-174 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,762,956 of ('956) in view US 5,023,084 ('084).

US '956 teaches a transdermal contraceptive delivery system comprising impermeable backing layer and adhesive matrix comprising combination of 17-β-estradiol and levonorgestrel, copolymer of 2-ethylhexyl acrylate and 3-60% of vinyl acetate, humectant, and combination of permeation enhancers comprising dimethyl sulfoxide, lauryl lactate and ethyl lactate (abstract; col.5, lines 37-60; col.6, lines 5-6, 47-48col.7, lines 50-60; col.9, lines 5-10col.16, lines 47-67).

US '956 does not teach the capric acid in the mixture of permeation enhancers.

US '084 teaches transdermal estrogen/progesterone absorption dosage unit comprising adhesive matrix comprising permeation enhancers. US '084 teaches capric acid as the preferred enhancing agent because it provides highly satisfactory skin absorption enhancement, (abstract; col.17, lines 25-57).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal delivery device to deliver combination of estrogen and progesterone in an adhesive polymer matrix comprising combination of enhancers comprising dimethyl sulfoxide, lauryl lactate and ethyl lactate as disclosed by US '956, and further add capric acid to the adhesive combination as disclosed by US '084, motivated by the teaching of US '084 that capric acid is a preferred enhancer for estrogen and progesterone combination because it provides highly satisfactory skin absorption enhancement, with reasonable expectation of having a transdermal delivery device comprises adhesive polymer matrix comprising a combination of dimethyl sulfoxide, lauryl lactate, ethyl lactate and capric acid with highly satisfactory skin absorption enhancement for the combination of estrogen and progesterone.

7. Claims 167-170 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '956 in view of US '084 as applied to claims 163-166 and 171-174 above, and further in view of US 6,007,835 ('835).

The teachings of US '956 and US '084 are discussed above.

However, the combination of the references does not teach polyvinyl pyrrolidone (PVP) or PVP copolymer with vinyl acetate (VA) as claimed in claims 167-170.

US '835 teaches transdermal delivery system for steroid hormones comprising and adhesive matrix comprising PVP/VA-S-630 that has content of 40% 0f VA and 60% PVP (abstract; col.4, lines 33-39). PVP/VA copolymer provides a matrix that exhibits the desired ergonomic and therapeutic properties, and makes it possible to obtain

remarkable yield (col.6, lines 12-16). PVP/VA copolymer enhances the solubility of the hormones, and surprisingly, makes it possible to enhance the adhesion of the matrix to the skin and also causes reduction in skin irritation (col.6, lines 35-41).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal delivery device to deliver combination of estrogen and progesterone in an adhesive polymer matrix comprising humectant and combination of enhancers comprising dimethyl sulfoxide, lauryl lactate, ethyl lactate and capric acid as disclosed by the combined teachings of US '956 and US '084, and replace the humectant by PVP/VA-S-630 copolymer disclosed by US '835, motivated by the teaching of US '835 that PVP/VA copolymer provides a matrix that exhibits the desired ergonomic properties with remarkable yield, enhances the solubility of the hormones, and surprisingly, makes it possible to enhance the adhesion of the matrix to the skin and also causes reduction in skin irritation, with reasonable expectation of having adhesive polymer matrix to deliver combination of hormones comprising combination of enhancers and PVP/VA-S-630 copolymer wherein the matrix exhibits the desired ergonomic properties with remarkable yield, enhances the solubility of the hormones, enhances the adhesion of the matrix to the skin and also causes reduction in skin irritation.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

Isis Ghali

ISIS GHALI
PATENT EXAMINER